1655

TRANSMITTAL FORM

(to be used for all correspondence after initial filing)

Total Number of Pages in This Submission	22

Application Number	10/542,127
Filing Date	12/20/2005
First Named Inventor	Yamini Bhushan Tripathi
Art Unit	1655
Examiner Name	Christopher Robin Tate
Attorney Docket Number	4544 - 052144

ENCLOSURES *(check all that apply)*

- ☐ Fee Transmittal Form
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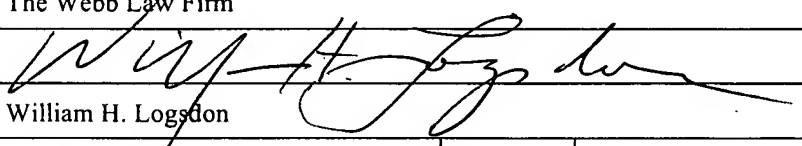
Remarks

The Commissioner for Patents is hereby authorized to charge any additional fees or underpayment of fees under 37 CFR 1.16 and 1.17 to Deposit Account No. 23-0650 .

SIGNATURE OF APPLICANT, ATTORNEY, OR AGENT

Firm Name	The Webb Law Firm		
Signature			
Printed Name	William H. Logsdon		
Date	May 20, 2008	Reg. No.	22132

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I hereby certify that this correspondence is being electronically transmitted to the USPTO or deposited with the United States Postal Service with sufficient postage as first class mail in an envelope addressed to: Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450 on the date shown below:

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Typed or printed name	Mary Ann Mulvihill	Date	May 20, 2008

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Firm Name	The Webb Law Firm		
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Printed Name	William H. Logsdon		
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Signature			
Typed or printed name	Mary Ann Mulvihill	Date	May 20, 2008

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Application No.	:	10/542,127	Confirmation No.	:	8251
Applicant	:	Yamini Bhushan Tripathi			
Filed	:	12/20/2005			
Title	:	A NOVEL POLYHERBAL PREPARATION FOR THE PREVENTION OF ATHEROSCLEROSIS AND HYPERLIPIDEMIA			
Group Art Unit	:	1655			
Examiner	:	Christopher Robin Tate			
Customer No.	:	28289			

Commissioner for Patents
P. O. Box 1450
Alexandria, VA 22313-1450

CLAIM FOR PRIORITY UNDER 35 U.S.C. §119

Sir:

Attached hereto is a certified copy of priority document 1255/DEL/2002 which corresponds to the above-identified United States application and which was filed in the Indian Patent Office on December 13, 2002.

I hereby certify that this correspondence is being electronically submitted to the United States Patent and Trademark Office on May 20, 2008.

05-20-2008 Mary Ann Mulvihill
Date Signature

Mary Ann Mulvihill
Typed Name of Person Signing Certificate

The priority benefits provided by Section 119 of the Patent Act of 1952 are claimed for this application.

Respectfully submitted,

THE WEBB LAW FIRM

By _____

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INTELLECTUAL PROPERTY INDIA

सत्यमेव जयते

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MINISTRY OF COMMERCE & INDUSTRY
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PLOT NO.-32, SECTOR-14, DWARKA
NEW DELHI-110076

Ph: 011-28081923 - 25
Fax: 011-28081920,40
Website: http://ipindia.nic.in
E-mail: delhi-patent@nic.in

I, the undersigned being an officer duly authorized in accordance with the provision of the patent Act, 1970 hereby certify that annexed hereto is the true copy of the ***Application Form & Complete Specification*** *in connection with Patent Application no. 1255/DEL/2002 dated 13.Dec.2002, Post dated 13.Jan.2003.*

Witness my hand this 02nd day of April 2008.

(Dr. Prithipal Singh)

Examiner of Patent and Designs
For Controller of Patents and Designs

FORM-1

1255

13 DEC 2002

(To be filed in Triplicate)

Application is Post-dated to 13/01/03 under Section 17 of the Patents Act, 1970

THE PATENTS ACT, 1970

(39 of 1970)

APPLICATION FOR GRANT OF A PATENT

[See Sections 5(2) 7, 54 and 135]

Asstt. Controller of Patents & Designs 10/05/07

1) DEPARTMENT OF BIOTECHNOLOGY, of Block 2, 7th Floor, CGO Complex, Lodi Road, New Delhi-110 003; and
2) BANARAS HINDU UNIVERSITY, of Varanasi-221 005, India.

2. hereby declare-

(a) that ~~I am~~ / We are in possessin of an Invention titled

Title: A NOVEL POLYHERBAL PREPARATION FOR THE PREVENTION OF ATHEROSCLEROSIS AND HYPERLIPIDEMIA

PUBLICATE

(b) that the ~~Provisional~~/ Complete Specification relating to this invention filed with this application.

(c) that there is no lawful ground of objection to the grant of a patent to me / us.

3. Further declare that the inventor(s) for the said invention is / are :

Surname first and then name of inventor/s:

TRIPATHI YAMINI BHUSHAN, of
Deptt of Medicinal Chemistry
Institute of Medical Sciences
Banaras Hindu University, Varanasi-221 005

4. ~~I~~/We, claim the priority from the application(s) filed in convention countries, particulars of which are as follows :

NA

5. I/We state that the said invention is an improvement in or modification of the invention the particulars of which are as follows and of which I/We are the application/patentee:

NA

6. I / We state that the application is divided out of my/our application, the particulars of which are given below and pray that this application be deemed to have been filed on ..... NA .....
under section 16 of the act.

7. That I am / We are the assignee of the true and first inventors.

8. That my / our address for service in India is as follows :
L S DAVAR & CO., 5/1, Kalkaji Extension, 1st Floor, New Delhi-110019 and
Monalisa, Flats IB & IC, 17, Camac Street,
Kolkata-700 017.
Phones : 247-3996, 247-5918, 280-5536
Fax No. : 91-33-247-5886, 240-6292
91-11-646-4443

9. Following declaration was given by the inventor(s) or applicant(s) in the convention country :

I / We the true and first inventors for this invention or the applicant(s) in the convention country declare that the applicant(s) herein is / are my / our assignee or legal representative.

Signature of the true and first Inventor/s or Applicant In the convention country with date, name to be given below Signature

TRIPATHI YAMINI BHUSHAN

10. That to the best of my / our knowledge, information and belief the fact and matters stated herein are correct and that there is no lawful ground of objection to the grant of patent to me / us on this application.

11. Following are the attachment with application :

(a) ~~Provisional~~/Complete specification (3 copies).

(b) Drawings 2 (Sheets) 3 copies.

(c) Priority document/s To Follow

(d) Statement and undertaking on Form 3 in dupl.

(e) Form 5. NA

(f) Power of Authority. To Follow

(g)

(h)

(i) Fee Rs. ~~1,500/-~~ /Rs. 5,000/- in cheque / bank draft. bearing No.....date.....

on.....Bank.

To be Signed by applicant or authorised patent agent

~~I~~/We request that a patent may be granted to ~~me~~/us for the said invention.

Dated this 12th day of December 2002

Signature (G S Davar)

of L S DAVAR & CO.,
Applicants' Agent

To
The Controller of Patents
The Patent Office
at NEW DELHI

1255-2

13 DEC 2002

FORM-2

THE PATENTS ACT, 1970

(39 of 1970)

~~PROVISIONAL~~/COMPLETE

SPECIFICATION

SECTION 10

DUPLICATE

TITLE

A NOVEL POLYHERBAL PREPARATION FOR THE PREVENTION OF ATHEROSCLEROSIS AND HYPERLIPIDEMIA

APPLICANT

1) DEPARTMENT OF BIOTECHNOLOGY, of Block 2, 7th Floor, CGO Complex, Lodi Road, New Delhi-110 003; and
2) BANARAS HINDU UNIVERSITY, Varanasi -221 005. India.

The following specification particularly describes the nature of the invention and the manner in which it is to be performed

FIELD OF INVENTION

This invention relates to a novel polyherbal preparation for the prevention of Atherosclerosis and Hyperlipidemia.

BACKGROUND OF INVENTION

Atherosclerosis is one of the major problems for young age death. It is an active process of inflammation and cell proliferation. It starts when normal vascular functions go away. Basically, there is blockage in the coronary artery, which leads to the heart attack. This blockage could be due to deposition of lipid, formation of wound or sudden release of lipid from the endothelial wall due to bursting of plaque. Slow and gradual deposition of fat in the intimal layer of artery is called fatty lesion or plaque. Slowly these fatty lesions get fibrosed and calcium is deposited in it. Initially, it is a reversible process but after fibrosis, it becomes irreversible. In fact, fat deposition in the blood vessel is a natural process with aging, but in some individuals, its rate of formation is significantly high and therefore leads to pathological state of coronary artery disease.

There are several reasons for this deposition. However, the basic cause is considered to be the faulty metabolism of lipid in the body. High cholesterol diet or high level of endogenous cholesterol synthesis in the body is the basic cause of artherosclerosis. Of course, there are several precipitating factors for this pathology, such as stress, smoking, diabetes, hypertension, age, male sex, family history leading to elevated homocystein, high serum lipoprotein-a and infection withcytomegalovirus or chlamydia. More free radical production leading to rapid oxidation of LDL, followed by the excess uptake of oxidised LDL by the macrophages leading to the formation of foam cells is the basic pathology.

PRIOR ART

As this disease is multi-factorial, there are several approaches to manage artherosclerosis. First and foremost, it is to reduce the lipid load in the body or to increase the HDL content or to reduce the burden of free radicals and oxidized LDL or to remove foam cells and fatty lesions. There are two major steps, (a) Prevention of the formation of fatty plaque; (b) Regression of plaque already formed. At present, there are two main approaches for the management of atherosclerosis (1) Invasive techniques; and (2) Non-invasive techniques. In the non-invasive group of techniques, the most prominent approach is to lower the blood lipid, specially the cholesterol and triglycerides. In this approach, the main pathway is to inhibit the endogenous cholesterol synthesis by blocking the HMG-Co synthase. A drug known is different kind of Statins. In this way, there is reverse cholesterol transport from the tissue to the blood leading to the lowering of the LDL and VLDL. Several medicinal plants products are also available with a hypolipidemic claims, eg. Commiphora mukul, Terminalia arjuna, Acorus calamus, etc.. In fact, ayurvedic literature discloses such plant names, but not much scientific study has been made with these plants.

Yet another approach is to increase the HDL in the blood. Unfortunately, there is no good medicine, which can increase the serum HDL. The exercise is the only way to achieve this goal. Use of cow butter/milk has also shown the property of raising serum HDL upto some extent, but it can not be used as a medicine in the patients of hyperlipidemia and artherosclerosis.

Third approach is to prevent the oxidation of LDL in the blood, because ox LDL is the basic cause of foam cell formation and thereafter its deposition in the arterial wall, forming artherosclerotic plaque. To achieve this goal, anti-oxidants are being recommended as the diet supplements. Although the use

of antioxidants has increased significantly as a diet supplement in the management of artherosclerosis and other coronary artery diseases, but does not fall in the group of therapeutic medicine, because of its non-specific role. Metal chelaters are also used to prevent the formation of free radicals, because iron mediated Fenton's reaction is one the basic cause of hydroxyl radical production.

After knowing the molecular pathway of atheroma formation, gene therapy is being tried in the management of this disease. It is reported that stable atheroma is not as dangerous as the unstable one. For this unstability, a group of proteases known as MMPs (Matrix Metallo proteinases) are responsible. In fact, they digest the fibrous cap of the plaque and allow the lipid to come out of the plaque and block the arterial blood flow.

Attempts are now being made to introduce the genes to inhibit these MMPs. Similarly, the most recent approach of gene therapy is to inhibit a growth factor M-CSF (Macrophage colony stimulating factor), which is responsible for the proliferation of smooth muscle cells and rapid formation of foam cell leading to their deposition.

One more approach to manage artherosclerosis is to regulate the inflammatory cytokines and various enzymes like lipoxygenase and cyclooxygenase, because inflammation is one of the basic factors, responsible for plaque formation.

Since artherosclerosis is a multietiological factor disease, so doctors recommend a series of medicine to manage this disease and still the disease is not manageable because of uncoordinated approach. However, there is no medicine which can target several etiological factors simultaneously by giving one tablet. The patient is supposed to take several medicines in a day, which gives him a kind of psychological depression. These medicines,w hen

given in isolation does not give significant impact on the prevention of atheromaformation, because other factors become more prominent. The genetherapy, which is being developed is at the infancy stage and if at all, it comes to the public use, it will be very expensive and also with several side effects, only the time will tell for its success.

There are many claims to prevent the formation of plaque, by reducing the risk factors, by taking more antioxidants or by lowering the cholesterol by the use of several hypolipidemic drugs like Statins, etc.. Once atheroma is detected, the coronary bypass, etc. are the only remedies. In fact, no good drug is available to regress the plaque, already formed.

OBJECTS OF THE INVENTION

An object of this invention is to propose a novel polyherbal preparation which has the capacity to target several etiological pathways, and finally lead to atherosclerosis.

Another object of this invention is to propose a novel polyherbal preparation which is anti-inflammatory, anti-oxidant and increases serum HDL, and more specifically, it inhibits Lox-15, Cox-2 and Ca^{--}deposition in the plaque, increases Collagen in the chronic plaques, increases serum HDL and decreases serum TG.

Still another object of this invention is to propose a novel polyherbal preparation which enhances serum HDL and prevents plaque formation even in the presence of high serum lipid.

Yet another object of this invention is to propose a novel polyherbal preparation which enhances the collagen tissue in the old plaque indicating towards the stabilisation of the plaque.

A further object of this invention is to propose a novel polyherbal preparation which inhibits the Cyclooxygenase-2 and lipoxygenase-15, which are responsible for atherosclerosis.

A still further object of this invention is to propose a novel polyherbal preparation which is cost-effective, more effective than its component medicinal plant and does not have any toxic or side effect with high therapeutic safety margin.

DESCRIPTION OF INVENTION

According to this invention, there is provided a polyherbal preparation for the prevention of atherosclerosis and hyperlipidemia comprising a mixture of Commiphora mukul, Boswellia serrata, Semecarpus anacardium Strychnos nux vomica, Termenalia arjuna and Shankha Bhusma.

The polyherbal composition may further include Rubia cordifolia, Bacopa monnieri, Triphala and Trikatu.

In accordance with this invention, the constituents are present in the following ratio :

Purified Commiphora mukul	1 to 4
Pure Boswellia serrata	0.5 to 4
Purified Semecarpus anacardium	0.1 to 0.4
Purified powder Strychnos nux vomica	0.4 to 2
Pure powder of water extract Termenalia arjuna	0.3 to 2
Shankha Bhusma	0.5 to 2

Further, any one or more of the following constituents are added in the following ratio :

Rubia cordifolia	0.05 to 1
or Bacopa monnieri	0.5 to 3

or Triphala	0.5 to 3
and Trikatu	0.5 to 3
Specifically, an advantageous ratio is :	
Purified Commiphora mukul	3.7
Pure Boswellia serrata	3.0
Purified Semecarpus anacardium	0.1
Purified powder Strychnos nux vomica	1.0
Pure powder-water extract Termenalia arjuna bark	0.7
Shankha Bhusma	1.5

EXAMPLE

Composition of atherogenic diet:

Atherogenic diet consists of cholesterol rich-rabbit chow, cabbage and gram in the same amount as in control rabbits. Atherogenic diet is made as follows:

The chow is powdered and mixed with the following items in a specific ratio as given below and again pellet is made. It is dried in oven and kept in refrigerator. At one time, diet was prepared only for 4 days.

Composition of diet:

Rabbit chow	57%
Milk powder	14%
Yeast powder	04%
Salt	01%
Multivitamin	0.1%
Cholesterol	05%
Hydrogenated fat	17%
Cholic acid	01%

Experimental details:

Male rabbits were randomly divided into 3 groups, having 12 animals in each. They were kept for 15 days for acclimatization in the laboratory condition. During this period, de-worming was done to each animal and Hostacycline and Vimeral was given in drinking water. The animals were divided into the following groups :

Control diet (CD)

Atherogenic diet (AD)

Atherogenic diet – BHUx 60mg/100g body weight (AD_{40})

Control diet consists of rabbit chow, cabbage and gram 400g/day and water ad libitum.

Atherogenic diet was given to the rabbits in the control group, 3 months later, BHUx was given in the experimental group alongwith the atherogenic diet for another 3 months. Therefore, total duration of the experiment was of 6 months. After every one month, lipid profile was carried out in blood and at the end of experiment, animal was sacrificed and heart, liver, kidney, dorsal aorta were saved. These tissues were processed for histological studies. Sections of 5 micron thickness were cut and stained with different stains. In the AD groups (Experimental control) only 2 ml of gum acacia suspension in distilled water (5%) was given in the similar way. Lipip profile was carried out by using Zydus Pathline kits (a group and Cadila Healthcare Ltd.) in terms of cholesterol, TG, LDL and HDL. After 3 months, animals were sactificed to collect heart and dorsal aorta

(A) Histology:

(1) Study with Dorsal Aorta – It was separated from the heart at the point of aortic arch origin and longitudinally cut open. It was stained in Sudan IV

stain. After making a tracing of the atherogenic patches, the tissue was fixed and processed for block preparation and section cutting.

(2) Study with aortic arch and coronary artery – Whole heart was divided into 2 parts, named H_1 and H_2. The upper H_1 part was cut at 6 u thickness and stained with Hematoxylin and Eosin (H&E). Microscopic study was made in the region of aortic arch and coronary artery with reference to intimal thickening. These sections were separately stained with specific stains for the visualisation of collagen tissue and calcium deposition.

(3) Study with kidney and liver – Sections were stained with H&E and with AgNO 3 separately to evaluate the degree of fibrosis and necrosis.

(B) Biochemical tests – Blood of each animal was selected and plasma/serum was isolated as per need to assay SGOT, SGPT, Alkaline phosphatase and complete lipid profile.

(C) In vitor assay – To study the effect of the preparation of the present invention on cyclooxygenase and lipoxygenase, in vitro enzyme assay was carried out by using standard oxygraph technique. The results show that the preparation of the present invention is more sensitive to Cox-2 inhibition than the Cox-1. Similarly, on Lipoxygenase assay, it showed high sensitivity to the 15-Lipoxygenase than the other isoenzymes.

Brief description of the accompanying drawings and tables related to result :

Fig.1 : Bar diagram showing lipid profile with raised HDL.

WE CLAIM:

1. A polyherbal preparation for the prevention of atherosclerosis and hyperlipidemia comprising a mixture of Commiphora mukul, Boswellia serrata, Semecarpus anacardium Strychnos nux vomica, Termenalia arjuna and Shankha Bhusma.
2. A polyherbal preparation as claimed in claim 1 wherein the constituents are present in the following ratio :

Purified Commiphora mukul	1 to 4
Pure Boswellia serrata	0.5 to 4
Purified Semecarpus anacardium	0.1 to 0.4
Purified powder Strychnos nux vomica	0.4 to 2
Pure powder of water extract Termenalia arjuna	0.3 to 2
Shankha Bhusma	0.5 to 2

3. A polyherbal preparation as claimed in claim 1 comprising Rubia cordifolia, Bacopa monnieri, Triphala and Trikatu.
4. A polyherbal preparation as claimed in claim 3 wherein the following constituents are added in the following ratio :

Rubia cordifolia	0.05 to 1
or Bacopa monnieri	0.5 to 3
or Triphala	0.5 to 3
and Trikatu	0.5 to 3

5. A polyherbal preparation as claimed in claim 1 wherein the constituents are present in the ratio of

Purified Commiphora mukul	3.7
Pure Boswellia serrata	3.0
Purified Semecarpus anacardium	0.1
Purified powder Strychnos nux vomica	1.0

Pure powder-water extract Termenalia arjuna bark	0.7
Shankha Bhusma	1.5

6. A polyherbal preparation as herein described and illustrated in the Examples.

Dated this 12th day of DECEMBER, 2002.

(G S DAVAR)
OF L S DAVAR & CO.
APPLICANTS' AGENT.

ABSTRACT

"A polyherbal preparation for the prevention of atherosclerosis and hyperlipidemia"

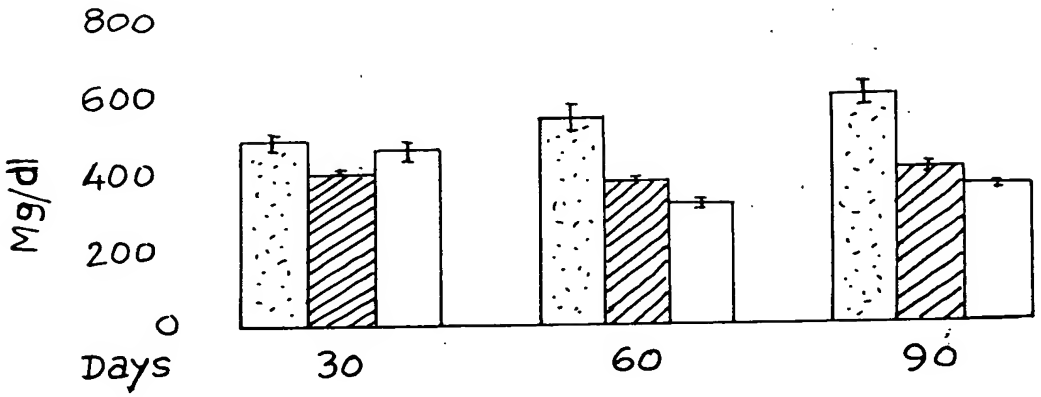
This invention relates to a polyherbal preparation for the prevention of atherosclerosis and hyperlipidemia comprising a mixture of Commiphora mukul, Boswellia serrata, Sem ecarpus an acardium Strychnos nux vomica, Termenalia arjuna and Shankha Bhusm a.

1. DEPARTMENT OF BIOTECHNOLOGY
BANARAS HINDU UNIVERSITY.

1255 2 SHEETS
SHEET 1

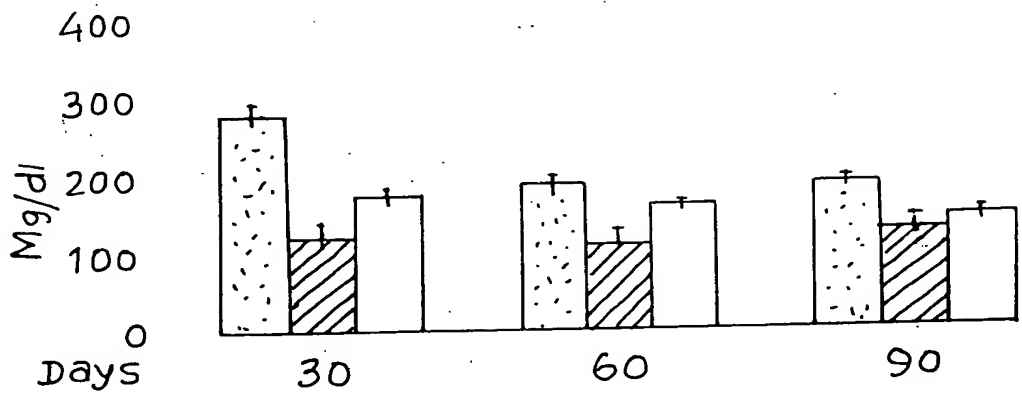
13 DEC 2002

Total Cholesterol



	30	60	90
AD	477.7	529.5	582
AD+10p	390.5	367.2	391.6
AD+60 p	451.7	306.9	346.6

Triglycerides



	30	60	90
AD	276	184.9	183.5
AD+10p	119	108	122.3
AD+60 p	171.8	157.4	140.1

Fig 1

OF L. S. DAVAR & Co.
APPLICANTS' AGENT

1. DEPARTMENT OF BIOTECHNOLOGY
2. BANARAS HINDU UNIVERSITY

1255-02

13 DEC 2002

HDL - Cholesterol

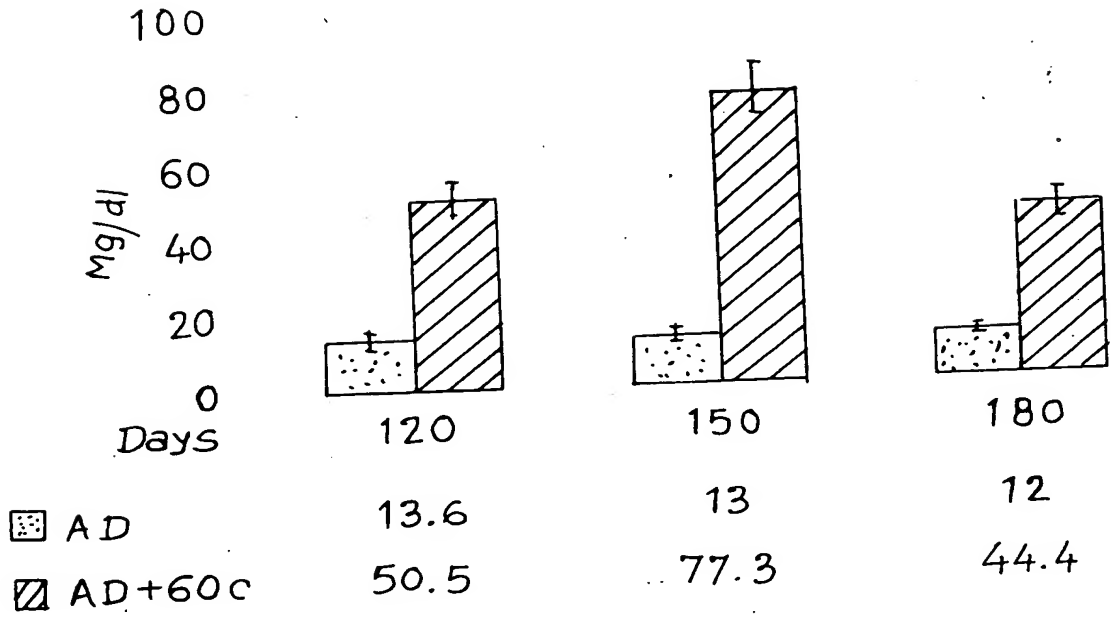
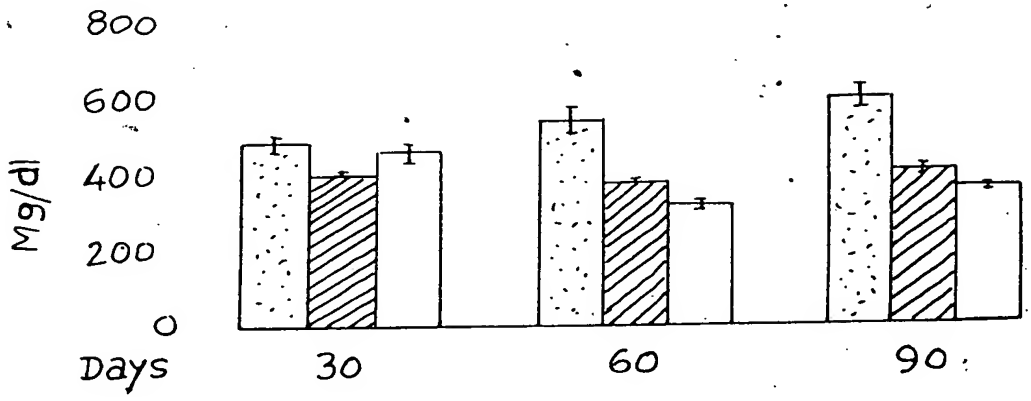


Fig. 1

OF L.S. DAVAR & Co.
APPLICANTS' AGENT

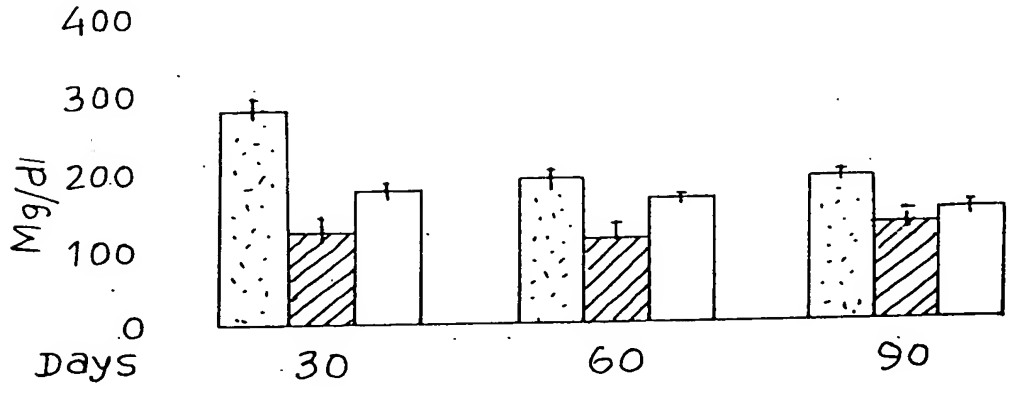
1. DEPARTMENT OF BIOTECHNOLOGY
2 BANARAS HINDU UNIVERSITY

Total Cholesterol



	30	60	90
AD	477.7	529.5	582
AD+10p	390.5	367.2	391.6
AD+60 p	451.7	306.9	346.6

Triglycerides



	30	60	90
AD	276	184.9	183.5
AD+10p	119	108	122.3
AD+60 p	171.8	157.4	140.1

Fig 1

OF L. S. DAVAR & Co.
APPLICANTS' AGENT